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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,795	11/13/2003	Rosanne Crooke	ISIS.003CP1	6394

20995 7590 07/26/2007
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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

NOTIFICATION DATE	DELIVERY MODE
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07/26/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/712,795	Applicant(s) CROOKE ET AL.	
	Examiner Janet L. Epps-Ford	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 125-145 and 197-212 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 142-145 and 197-212 is/are allowed.
- 6) ☒ Claim(s) 125, 126 and 129-141 is/are rejected.
- 7) ☒ Claim(s) 127 and 128 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
2. Claims 125-145 and 197-212 are presently pending.
3. The previously indicated allowability of claims 125, and 129-141 is withdrawn in view of the new grounds of rejection set forth below.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/426,234, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The disclosure of provisional application 60/426,234 does not provide adequate support for SEQ ID NO: 247, or antisense oligonucleotides 14 to 30 nucleobases in length comprising at least 14

contiguous nucleotides of SEQ ID NO: 247. Thus the earliest priority date available for the instant claims is the filing date of PCT/US03/15493, May 15, 2003.

New Grounds of rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 125-126 are rejected under 35 U.S.C. 102(a) as being anticipated by Hayashi et al. (JP2002355074-A).

Hayashi et al. discloses a twenty base pair nucleic acid that comprises a 15 base pair contiguous stretch of nucleotides that are 100% identical to 15 contiguous nucleotides of SEQ ID NO: 247.

The phrase “antisense compound” or “antisense oligonucleotide” set forth in the instant claims is interpreted as an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, although the nucleotide sequence structure disclosed in Jarvis et al. is silent in regards to its use as an antisense compound, absent evidence to the contrary, the prior art nucleotide sequence meets all the structural requirements of the instant claim, and thus anticipates the claimed invention.

The oligonucleotides of Hayashi et al. are disclosed as useful as hybridization probes or PCR primers. Moreover, the oligonucleotides of this reference are disclosed as "specific" for *Enterohemorrhagic E. coli* O157:H7.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 125-126, and 129-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi et al. in view of by Bennett et al. (US Patent No. 6172216), Dempcy et al. (US 6,949,367) and Simeonov et al.

The discussion of Hayashi et al. as set forth above is incorporated here. However, Hayashi et al. does not teach wherein the disclosed oligonucleotides are modified as set forth in the instant claims.

Bennett et al. teach that the incorporation of modified nucleobases into oligomeric compounds, including 5-methylcytosine modifications, is well known in the art for the purpose of increasing the binding affinity of the oligomeric compounds of the invention. (col. 9, lines 5-7). Bennett et al. also discloses wherein the oligonucleotide is a chimeric oligonucleotide, comprising 2'-MOE modifications (other positions comprise 2'-deoxy modifications), all 2'-MOE cytosines are 5-methylcytosines, and all linkages are phosphorothioate linkages. Bennett et al. also teach oligomeric compounds of comprising sodium salts, see for example, col. 11, lines 14-23. Additionally, Bennett et

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al. includes compositions comprising the disclosed oligomeric compounds in combination with a carrier or diluent, see col. 14.

Dempcy et al. teach the use of 2'-O-methoxyethyl modifications in oligonucleotides, wherein the modified oligonucleotides exhibit increased mismatch discrimination (col. 52, lines 2-17).

Simeonov et al. teach the use of oligonucleotide primers bearing locked nucleic acid-modifications in application of allele specific PCR. Simeonov et al. concluded that primer probes bearing LNA modifications have superior properties in the discrimination of single nucleotide variations.

It would have been obvious to the ordinary skilled artisan at the time of the instant invention to combine the teachings of Hayashi et al., Bennett et al., Dempcy et al. and Simeonov et al. in the making of the claimed invention. One of ordinary skill in the art would have been motivated to make this modification since the oligonucleotides of Hayashi et al. are disclosed as useful as hybridization probes, and are "specific" for *Enterohemorrhagic E. coli* O157:H7, and the modifications of Bennett et al. are useful for increasing binding affinity of an oligomer, and Dempcy et al. and Simeonov et al. are specifically disclosed as useful for increasing the properties of modified oligonucleotides for discrimination of nucleotide variations.

Conclusion

9. Claims 127-128 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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10. Claims 142-145, and 197-212 are allowable over the prior art cited.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE